

**HUMAN SCIENCES RESEARCH COUNCIL
RESEARCH ETHICS COMMITTEE (REC)
TERMS OF REFERENCE**

PREAMBLE

The HSRC Research Ethics Committee (hereafter referred to as HSRC REC, or REC) was established by the governing body of the Human Sciences Research Council (HSRC) in August 2002. The HSRC REC is mandated to fulfil its function by the Board of the HSRC, to which it reports on an annual basis.

The function of this committee is to promote research ethics and research integrity in the organization, and will primarily fulfill this function through independent, prospective and ongoing ethics review of all social science and humanities research projects undertaken by members of staff of the HSRC.

Provided there is no more suitable or eligible REC in South Africa and, subject to capacity and certain terms and conditions, the HSRC's REC is available to review, advise on, and approve or reject research protocols involving human participants within the borders of South Africa that are submitted to it by researchers who are not members of staff of the HSRC. In such instances, the ethics review is undertaken according to approved conditions.

No retrospective (post ex facto) ethics approval can or will be granted.

1. REGISTRATION AND ACCOUNTABILITY OF THE REC

- 1.1 The National Health Act (Act 61 of 2003) established a National Health Research Ethics Council (NHREC) within the South African National Department of Health and mandates that every institution, health agency and health establishment at which health research is conducted must establish or have access to a REC registered with the NHREC.

A significant proportion of the research conducted at the HSRC and reviewed by the HSRC REC constitutes health research (as defined by The National Health Act, Act 61 of 2003), and it is therefore appropriate that the HSRC REC is registered with the NHREC, to which it also reports annually. The HSRC REC also maintains US Office of Human Research Protections Federal Wide Assurance accreditation (FWA 00006347, IRB No. 00003962).

- 1.2 The overarching ethics guidance for the HSRC REC will be the South African National Department of Health (2015) *Ethics in health research: Principles, processes and structures*. Where relevant, major international guidelines (including, but not restricted to: The Declaration of Helsinki, current version; The Belmont Report; and the Council for International Organizations of Medical Sciences [CIOMS] Guidelines) will apply. When strict compliance with the letter of a particular requirement of these declarations and codes is not possible, HSRC REC will ensure that the proposed research is nonetheless in keeping with the spirit of the declarations and codes.

- 1.3 The following National Legislation are applicable:
Constitution of the Republic South African, 1996
Human Sciences Research Council Act, Act 17 of 2008.
- 1.4 The HSRC REC is not directly involved in research misconduct cases but, given its registration with the NHREC, may advise the HSRC Deputy Chief Executive Officer (CEO) of Research to initiate disciplinary steps against researchers who violate either national or the HSRC REC's ethical guidelines as outlined in HSRC Research Policy. This includes instances where an HSRC staff member conducts social or health-related research involving human participants without prior ethics approval.

2. MANDATE

- 2.1 The HSRC REC functions as the official REC of the HSRC. The essential purpose of HSRC REC is to protect the dignity, rights, safety and well-being of all human participants in research.
- 2.2 In its review of all research projects (involving social science, humanities and health) undertaken by members of staff of the HSRC, the HSRC REC aims to provide independent, comprehensive and timely review of the ethics of proposed studies.
- 2.3 HSRC REC members must ensure that research proposals adhere to scientific and ethical standards as dictated by the disciplines concerned. Members are expected to be as objective and informed as can reasonably be expected of persons fulfilling this role.
- 2.4 Roles and responsibilities:
In line with international ethics standards as well as the commitment of the HSRC to ensuring ethically sound research, the REC wishes to highlight the following points that are pertinent to fulfilling its role diligently and accountably:
- The REC upholds the principle that the primary responsibility for ethically sound research practice and protection of participants resides with researchers.
 - The role of the REC is to support and guide researchers towards better or best ethical research practice. The REC is in this way a resource in the HSRC for researchers.
 - The REC approaches the ethical review of proposals in a collaborative spirit in order to arrive at decision making that involves the researchers.
 - The main purpose of questions or queries from members of the REC is to clarify or better understand researchers' intentions in order to assist it in working together with researchers towards solutions.
 - The comments made and questions asked by any one member of the REC are important to the deliberations of the REC as a whole.

3. MEMBERSHIP

- 3.1 Composition: The composition of HSRC REC will be in accordance with the provisions of the National Department of Health (2015) *Ethics in health research: Principles, processes and structures* and international guidelines for the composition of Institutional Review Boards (IRBs). Members of the HSRC REC should collectively have the qualifications, experience and expertise

to review and evaluate the scientific, legal, psychosocial and ethical aspects of research proposals.

3.2 Members of the HSRC REC are selected and appointed in terms of guidelines included in the Standard Operating Procedures (SOP). They adhere to a code of conduct.

3.3 Selection and appointment:

At least 40%, and a minimum of five, members of the REC should be external to the HSRC. External members are appointed by the CEO following a formal recruitment and selection process. Additional external members may be co-opted at the motivated request of the REC chairperson. This proposed additional route is to provide for selection of community members or e.g. members from other institutions attending for a limited term for capacity building purposes.

Other REC members are internal to the HSRC, and are selected as follows: One researcher from each research unit, nominated by the Executive Director (ED) or head of unit to be a member, with the possibility of one or more alternates available from each research unit to share the load of reviewing protocols and attendance at meetings. Of the unit representatives, one must be at a level of Research Specialist or above; the others should be experienced researchers at any level.

The CEO ensures that representation across the units provides diversity as well as coverage of the disciplines and methodologies of the human and social sciences and that the REC is broadly representative.

The list of appointed REC members is submitted to the Board for ratification.

Appointment letters will be signed by the CEO and include the professional liability insurance to cover both affiliated and non-affiliated members when carrying out any professional duties under the auspices of the HSRC REC. All REC members will sign confidentiality agreements in their appointment letters.

3.4 Only external members of the Committee will be remunerated in accordance with HSRC policies.

3.5 Chairperson and deputy-chairpersons: The chairperson and one deputy-chairperson of the REC should be external members. The other deputy-chairperson should be internal to the HSRC. The chairperson is appointed by the CEO. Deputy-chairpersons are also appointed by the CEO, as advised by the REC chairperson following due consultation with REC members.

3.6 Functions of the chairperson include approving proposals that do not require substantial review, allocating each proposal to at least two members of the REC besides him/herself for detailed review, granting exemption from review where appropriate, and arranging expedited reviews in exceptional circumstance (as outlined in the SOP).

3.7 The chairperson may request one of the deputy chairpersons to fulfil the above functions in the absence of the chairperson.

3.8 Number of members and quorum:

The total number of REC members must be no less than 10. At least five members of the REC should be external to the HSRC.

If the REC consists of more than 15 members, the quorum shall be 33% with at least one internal member and at least one external member present.¹

If the REC consists of 15 members or less, the quorum shall be 50% +1 (a simple majority)².

3.9 Term of office: REC members serve for a three-year term of office, which may be renewable twice. Should a member have completed three consecutive terms, such a member should stand down for at least one term.

3.10 The REC has powers to consult with external individuals or HSRC researchers with specialised knowledge if the expertise of the standing REC is considered to be lacking specialised experience for a given task, provided they are not conflicted in relation to the study under consideration and subject to confidentiality assurances. The REC may also consider involving an advocate for special interest groups of participants proposed for particular research, should such involvement be deemed as adding value to the review process for informed responsible decision making in the context.

The HSRC REC may also consult with other RECs if appropriate, bearing in mind confidentiality constraints.

4. Independence of the Committee

Independence of the Committee is guided by international and institutional norms.

Researchers, sponsors, and funders may attend a REC meeting to answer questions about their research protocols and associated documents, but they are not present when the REC reaches decisions about their proposed research.

Senior decision-makers of the entity creating the REC, or of any organisation that sponsors or conducts the research reviewed by the REC (such as the director of an institution, or his or her agent), do not serve as members of the REC.

The entity that establishes the REC ensures that REC members are protected from retaliation based on positions taken with respect to REC-related matters or review of research projects.”

5. Code of Conduct for members of the HSRC REC³

5.1 All members of the HSRC REC are required to affirm in writing their commitment to the following:

5.1.1 To diligently perform all responsibilities arising from their membership of the REC.

¹ The current number of members is 17. Hence a quorum is 33% of 17, namely 6.

² In the event that the calculation comes to 0.5 of a person, rounding shall be upwards, i.e. 7.5 will be 8.

³ Adapted from the University of Pretoria “Code of Conduct for members of the Faculty of Health Sciences Research Ethics Committee”

- 5.1.2 To regularly and punctually attend meetings of the REC. Members who are absent for three consecutive meetings without apology will be requested to step down.
- 5.1.3 To review accountably and reliably the research studies assigned to them.
- 5.1.4 To act constructively and with integrity in all REC-activities.
- 5.1.5 To make decisions and conduct their oversight responsibilities in an independent manner, free from bias and undue influence.
- 5.1.6 To maintain confidentiality regarding the research studies reviewed by the REC, and the deliberations at REC meetings.
- 5.1.7 To raise and have recorded in the REC minutes a vote of dissent in case of a legitimate concern, but abide by the majority resolution of the REC.
- 5.1.8 To consider and declare any prior interest and/or involvement in any matter being considered at a REC meeting to avoid potential conflict of financial or personal interest.
- 5.1.9 To abide by decisions of the REC on how such a declared actual or potential conflict of interest should be managed.
- 5.1.10 To familiarise themselves with relevant policies of the HSRC as well as national and international research ethics guidelines.
- 5.1.11 To maintain their REC responsibilities in accordance with national and international regulatory requirements and within provisions of South African laws.
- 5.1.12 To provide the REC's administrative office with an abbreviated CV regarding their ethics training and experiences at the beginning of their term and to complete annually research ethics training to maintain their knowledge and keep abreast of latest

6. CONFLICT OF INTEREST

- 6.1 HSRC REC members should disclose actual, apparent or potential conflicts of interest to the REC. Conflicts of interest include direct benefits, such as secondary access of data originating from the research, or indirect involvement, such as assistance with protocol development, provision of material or facilities, or the support of individuals. A declaration of interest by all members will be completed at each meeting and managed accordingly
- 6.2 Members are required to sign a *conflict of interest agreement*. Any member of the REC who declares a conflict of interest with the submitted protocol, must recuse him/herself from the meeting when discussion and decision-making occurs on the protocol in which the member is directly involved as an investigator. Members may not use their membership to elicit an advantage.
- 6.3 A declaration of interest by all members will be completed at each meeting and managed accordingly. A member who is directly involved in a study conducted by a research unit will not be part of decision-making on that study. When a study from a member's unit is discussed, he/she may provide information for clarification but will not participate in decision-making if he/she is

directly involved. Offering clarification will not necessarily give that application an unfair advantage as any researcher may be invited to meetings to provide clarification. Clarification will be managed in an open and transparent manner.

7. CONFIDENTIALITY

- 7.1 All matters pertaining to the documents reviewed will be dealt with as confidential by all members of the HSRC REC and will not be distributed to a third party, unless required for approved external review or by law.
- 7.2 All members, at time of appointment, will sign a confidentiality agreement regarding meeting deliberations, applications, and information on research and related matters